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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,099	01/16/2001	Rebecca E. Cahoon	BB 1159	3054

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/744,099

**Applicant(s)**

CAHOON ET AL.

**Examiner**

Christian L Fronda

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34-42 and 46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-42 and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Claims 34-42 and 46 are under consideration in this Office Action.

#### *Claim Rejections - 35 U.S.C. § 101*

2. Claims 34-42 and 46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicants' arguments filed 06/23/2004 have been fully considered but they are not persuasive. Applicant's position is that there is no reason to doubt that the disclosed isolated polynucleotide encodes a polypeptide that has 3-dehydroquinate synthase activity and a deduced amino acid sequence of SEQ ID NO: 6; an enclosed BLASTP computer analysis shows 57% identity between SEQ ID NO: 6 and a the amino acid sequence of an *E.coli* 3-dehydroquinate synthase; and the specification discloses an asserted utility of the polypeptide in antibody production. The Examiner respectfully disagrees for reasons of record as supplemented below.

A "specific utility" is specific to the subject matter claimed which contrasts with a general utility that would be applicable to the broad class of the invention. "Substantial utility" is one that provides a specific benefit in currently available form at the time of filing of the invention. Utilities that require or constitute carrying out further research to identify and/or reasonably confirm a specific use are not substantial and do not provide a specific benefit. See MPEP 2107.01.

The asserted utility of the polypeptide in antibody production is a generic utility that is applicable to any polypeptide; and thus is not a specific utility of the claimed invention. The BLASTP computer analysis shows a low identity to a polypeptide known in the prior art with a known biological function. However, the specification does not disclose that any homology to a reference polypeptide known in the art is a disclosure that the claimed polypeptide automatically has the properties and biological function of the reference polypeptide relied upon. The specification does not disclose the **specific** function of the protein of SEQ ID NO: 6 or any activity assays to demonstrate that the protein has 3-dehydroquinate synthase activity.

The state of the state of the art in protein function prediction from protein amino acid sequence and structure is reviewed by Whisstock et al. (Q Rev Biophys. 2003 Aug;36(3):307-40). Whisstock et al. teach (1) protein function prediction is a difficult problem since homologous proteins often have different and multiple functions; (2) methods for inferring function based on similarity in sequence and/or structure between an unknown protein and one or more well-understood proteins is tenuous and only provide guesses at function; (3) protein function predictions suggest function but do not determine function; (4) the most useful effect of

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protein function prediction is to guide laboratory experimentation to confirm, refute, or correct the prediction; and (5) protein function prediction from protein sequence and structure is useful but is not a substitute for laboratory experimentation (see entire publication, especially pp. 321-335).

In view of the disclosure and state of the art in protein function prediction stated above, one of ordinary skill in the art would not recognize that claims 34-42 and 46 have a specific or substantial asserted utility or a well established utility since the only recognized utility of the claimed polynucleotide and polypeptide is to carry out further research to identify and/or reasonably confirm the specific biological function associated with the claimed polynucleotide and polypeptide. Since the claimed polynucleotide lacks utility, then the claimed vector, chimeric gene, host cell, and method of making the polypeptide using the claimed polynucleotide also lack utility.

### ***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

3. Claims 34-42 and 46 stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above in the rejection of claims 34-42 and 46 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Claims 34-42 and 46 which encompass any isolated polynucleotide encoding a polypeptide having 3-dehydroquinase synthase activity, wherein the amino acid sequence of the polypeptide and the amino acid sequence of SEQ ID NO: 6 have at least 80%, 90%, or 95% identity based on the Clustal alignment method are not enabled by the specification.

Applicants' arguments filed 06/23/2004 have been fully considered but they are not persuasive. Applicant's position is that the references of Bischoff et al. and Carpenter et al. combined with the specification enable one of skilled in the art to make the invention. The Examiner respectfully disagrees for reasons of record as supplemented below.

Carpenter et al. only shows nine catalytic residues are identified as being conserved while the entire protein is composed of 437 amino acids. The specification as originally filed does not identify the other amino acid residues that can be changed without any loss of enzyme activity. Furthermore, the specification provides guidance for screening and searching for the claimed invention which is not guidance for making the claimed invention. The Bischoff et al. reference teaches screening and searching which is not guidance for making the claimed invention.

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Thus, searching for the specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) in any polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO: 6 in order to make a polypeptide that has an amino acid sequence has at least 80%, 90%, or 95% identity to SEQ ID NO: 6 is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polynucleotide encodes a protein that has 3-dehydroquinate synthase activity is extremely low since no information is provided by the specification regarding the specific amino acid residues that can or cannot be changed without any loss of enzyme activity. Claims 39-42 and 46 which depend from defective claim 34 are also rejected because they do not correct the defect of claim 34.

Amending the claims to recite that the isolated polynucleotide encodes a dehydroquinate synthase comprising the amino acid sequence of SEQ ID NO: 6 may overcome the rejection.

### *Conclusion*

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

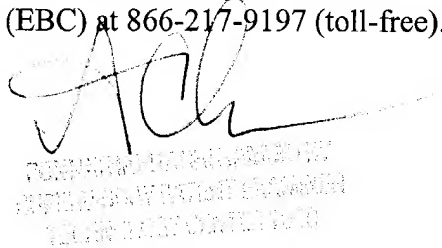
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



Handwritten signature: *ACH*  
Official stamp: **COMMUNICATIONS SECTION**  
**ATTENTION: PATENT EXAMINER**  
**TELEPHONE ROOM**